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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,684	11/08/2001	Aristo Vojdani	IMSCI2.005A	9590

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,684	VOJDANI, ARISTO	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2006 has been entered.

Response to Amendment

2. Applicant's amendment of claim 1 is acknowledged and has been entered.

3. Applicant's cancellation of claim 2 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With respect to claim 1, applicants recite an antibody that is an immune complex. However, according the specification, an immune complex is formed when antigens bind with antibodies (p.7, pg.24). Therefore, it is unclear if applicants are claiming antibodies directed toward the immune complex, or the antibody in the immune complex itself. Currently, based on

the recitation of the claims, it is believed that applicants are referring to the immune complex itself, and therefore mean the antibody in the immune complex.

7. With respect to claim 1, the recitation of optimal conditions is ambiguous. More specifically, the term optimal conditions does not appear to be defined in the specification, and the term itself would be considered to be subjective and open to interpretation. Currently, it is assumed that "optimal conditions" refers to healthy and normal.

8. With respect to claim 12, it is unclear if applicant intends to limit the first set of antibodies to a single antibody. This is also applicable to claims 10, 11 as it is unclear if applicants are limiting the set only to antibodies that bind to lupus peptide or arthritis. Furthermore it would be greatly appreciated if applicants could clarify whether the determination of the level of antibodies is performed for all the antibodies recited in the first and second set, or if it only performed for a single antibody in each set.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically while the specification, in particular fig. 6, discloses the determining the levels of myosin antibody, oxidized LDL antibody, heat shock protein-60

antibody, and β-2 glycoprotein-1 antibody, lupus peptide antibody, arthritis peptide antibody and immune complexes to determine the **possibility** of autoimmune disease and/or the **possibility** of cardiovascular disease with autoimmune disease, no support could be found for the actual **presence** of autoimmune disease and/or the **presence** of cardiovascular disease with autoimmune disease.

11. Claims 1, 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, applicant has recited antibodies comprising immune complexes in the second set. However, in the specification, applicant has merely defined immune complexes as when antibodies bind to antigens (p.7, pg.24). Applicants, however, have not defined what the antibodies are. Therefore, immune complexes would be formed when any of the antibodies in the first or second set bind to their respective antigens, and therefore anyone performing the method would always detect a higher than normal level of immune complexes whenever a higher than normal level of any of the antigens in the first or second sets is detected. Therefore it is not clear how one of ordinary skill in the art could associate immune complexes with just possible autoimmune disease, or even possible autoimmune and cardiovascular disease.

12. Claims 1, 3-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting immune complex disease, systemic lupus erythematosus, and arthritis, or the lack thereof, and detecting the diseases associated with myosin, oxidized LDL, and β-2 glycoprotein-1, or the lack thereof, the specification does not

reasonably provide enablement for detecting all autoimmune and cardiovascular diseases, or optimal conditions. In particular, even should the assay be negative for immune complexes, lupus peptides, arthritis peptide, myosin, oxidized LDL, and β-2 glycoprotein-1, the patient would not necessarily be optimal or even free of autoimmune and cardiovascular diseases. The patient could still suffer from Chlamydia-mediated heart diseases, diabetes, platelet related autoimmune diseases, and so on, where the markers for these diseases have not been tested for. Currently, applicants appear to only have support for a method for determining the possibility of immune-complex related diseases, systemic lupus erythematosus, and arthritis, and/or the possibility of immune-complex related diseases, systemic lupus erythematosus, and arthritis and the diseases associated with myosin, oxidized LDL, and β-2 glycoprotein-1, or the lack of the specified diseases.

13. According to Strongin (Strongin, Sensitivity, specificity, and predictive value of diagnostic tests: definitions and clinical applications, 1993, Laboratory Diagnosis of Viral Infections, p. 211-219), a number of characteristics need to be considered in the development of any suitable diagnostic assay. These characteristics include the sensitivity of the assay, the true-positive test rate, the false-negative test rate, the specificity, the true-negative test rate, the false positive test rate, the predictive value, the prevalence, the efficiency or percentage of all results that are true, and the accuracy of the recited diagnostic assay. However, none of these characteristics appear to have been considered.

Additional considerations must also be examined to enable the clinician to practice the invention, including assessment of when the maximum sensitivity, maximum specificity, and maximum efficiency are desired, how is the maximum sensitivity or specificity achieved, and

how is the predictive value maximized. An essential understanding of these factors is required to enable the skilled artisan to accurately use and interpret any given diagnostic test. Specifically, the specification fails to disclose what is meant by the possibility of autoimmune disease or by the possibility of cardiovascular disease with autoimmune disease. In particular it is unclear how much more likely a patient with the possibility of autoimmune disease or cardiovascular disease with autoimmune disease would become afflicted with those diseases compared to a patient without the possibility possibility of autoimmune disease or cardiovascular disease with autoimmune disease

Response to Arguments

14. Applicant's arguments with respect to claims 1, 3-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE 07/21/06
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